

REMARKS

Claims 1-17 are pending in this application. Of these claims, claims 9-17 have been withdrawn in view of the restriction requirement issued by the Examiner. Claims 1-8 remain. Claim 1 was previously amended.

Claims 1-8 have again been rejected under 35 U.S.C. § 102(b) as being anticipated by Gast '405. The Examiner argues that Gast discloses the combination of trimegestone and lactose. These claims have also been rejected under 35 U.S.C. § 103(a) as unpatentable over Gast, since Gast further teaches a hormonal product. Applicants submit that these rejections should be withdrawn since Gast neither teaches nor suggests the claimed invention.

Gast discloses a well-known phasic oral contraceptive including a progestin and an estrogen. According to the contraceptive regimen taught by Gast, a combination of an estrogen and a progestin is administered for 23-25 days followed by 3-5 days of estrogen-only administration. In addition to the progesting and estrogen hormones, each tablet administered in the regimen taught by Gast further includes components such as colorants, lubricants, fillers and the excipient lactose. All of these components are well known in the art of formulating oral contraceptives.

Gast nowhere teaches or suggests a formulation wherein the steroid hormone in the formulation is in non-crystalline form and wherein the hormone is stabilized in that form by the excipient. Gast also fails to provide any teaching or suggestions regarding the improved dissolution rate and release rate profiles achieved with a formulation comprising a steroid hormone stabilized in non-crystalline form by an excipient such as lactose. Gast simply lists the ingredients that comprise his Example 1 and Example 2 formulations. Only by reconstructing Gast with applicants' own teachings can the Examiner argue that this reference teaches the claimed invention. Such hindsight reconstruction is clearly impermissible and cannot form the proper basis for a rejection issued under § 102 or § 103.

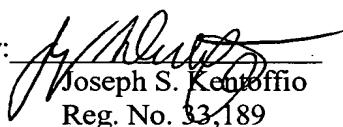
In view of the foregoing, applicants believe that claims 1-8 are in condition for allowance and respectfully request that a Notice of Allowance directed to these claims be issued at the earliest possible date.

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Applicants do not believe that any fees are required in connection with this Response. However, should any such fees be required, please charge Deposit Account No. 10-0750/ORT-1548/JSK.

Should the Examiner have any questions regarding this Response, please contact the undersigned attorney at the telephone number listed.

Respectfully submitted,

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